## REMARKS

Applicants have carefully studied the Office Action mailed on April 22, 2002, which issued in connection with the above-identified application. The present response is intended to be fully responsive to all points raised by the Examiner. Favorable reconsideration and an early action on the merits is respectfully requested.

Claims 1-41 are pending and at issue in this application.

In the Action, the Examiner required restriction to one of the following Groups of claims under 35 U.S.C. § 121:

Group I: Claims 1-14, drawn to an expression plasmid (class 536, subclass 23.72).

Group II: Claims 15-32 and 39, drawn to a minimum plasmid-based system to produce a virus[1] (class 435, subclass 235.1).

Group III: Claims 33-38 and 41, drawn to methods of making a viral vaccine[2] (class 424, subclass 204.1).

Group IV: Claim 40, allegedly[3] drawn to a mixed RNA negative-stranded virion (class 435, subclass 236).

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[1] Applicants respectfully note that, in the Office Action, the Examiner has incorrectly defined the scope of the claims of Group II. Thus, the claims of this group also encompass (i) host cells comprising the plasmid-based system, (ii) methods for producing virions using said host cells, and (iii) a method for generating an attenuated negative strand RNA virus using the plasmid-based system.

[2] Applicants respectfully note that, in the Office Action, the Examiner has incorrectly defined the scope of the claims of Group III. Thus, the claims of this group also encompass (i) methods for vaccinating a subject against a negative strand RNA virus and (ii) a composition comprising a negative strand RNA virus virion.

[3] Applicants respectfully note that, in contrast to the Examiner's determination, this claim is drawn to a composition comprising such virion.

In the Office Action, the Examiner contends that the inventions are distinct because allegedly (i) the inventions of Groups I and II are drawn to related subcombinations which can have different utility; (ii) the inventions of Groups I and III are drawn to different products; (iii) the inventions of Groups I and IV are drawn to different products (the invention of Group IV is drawn to a virus and not to a plasmid recited in the claims of Group I), and (iv) the inventions of Groups II and III are related as product and process of use, but the virus used to make the vaccine recited in the claims of Group III can be made by another process than the process recited in the claims of Group II.

In order to be fully responsive to the Requirement for Restriction, applicants hereby elect, with traverse, to prosecute the claims of Group II (claims 15-32 and 39) directed to (i) a minimum plasmid-based system to produce a virus, (ii) host cells comprising the plasmid-based system, (iii) methods for producing virions using said host cells, and (iv) a method for generating an attenuated negative strand RNA virus using the plasmid-based system.

Although applicants are making the above election to be fully responsive to the Requirement for Restriction, applicants respectfully traverse the Requirement and reserve the right to petition therefrom under 37 C.F.R. § 1.144. In particular, applicants respectfully request reconsideration of the Restriction Requirement to allow prosecution of all pending claims in the same application, or, in the alternative, modification of the Requirement to allow prosecution of more than one of the above groups, for the reasons provided as follows.

Under 35 U.S.C. § 121, "two or more independent and distinct inventions . . . in one application may . . . be restricted to one of the inventions". Inventions are "independent" if

there is no distinct relationship between the two or more subjects disclosed" (MPEP 802.01). The term "distinct" means that "two or more subjects as disclosed are related . . . but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER" (MPEP 802.01, July 1988) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification;

2. Separate status in the art; or,

3. Different field of the search.

Moreover, according to Patent Office examining procedures, "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803) (emphasis added).

Applicants respectfully submit that Groups I-IV fail to define inventions that warrant separate examination and search. Indeed, claims of Groups II and IV are classified in the same search class (435). Accordingly, searches of claims within these two groups will be coextensive. In addition, as provided below, the claims in Groups I-IV contain a number of unifying features.

Thus, applicants respectfully note that the expression plasmid recited in the claims of Group I is used to produce the minimum plasmid-based system recited in the claims of Group II. For example, claim 15 (Group II) recites all features of the expression plasmid of claim 1

(Group I), *i.e.*, the presence of an RNA polymerase I (pol I) promoter and terminator sequences, which are inserted between an RNA polymerase II (pol II) promoter and a polyadenylation signal. Consequently, a proper examination of the claims of Group II will necessarily require examination of the claims of Group I. Restriction of these two groups is unnecessary and illogical.

Applicants also respectfully submit that, as correctly noted by the Examiner at page 2 of the Office Action, the claims of Groups II and III are related as product and process of use. Indeed, claims 33 and 41 (Group III) recite virions produced by the method of claim 29 (Group II). It follows, that a single search of the features recited in the claims of Group III would necessarily and unescapably require a search of the subject matter of the claims of Group II, and therefore the examination of these groups of claims in the same application would not impose any additional burden on the Examiner. Moreover, the process claims of Group II are directed to a biotechnological process, necessitating consideration of claims of Group III directed to the product of this process. Sec. 35 U.S.C. §103(c). The Examiner lacks the authority to contravene this statutory provision and restrict Groups II and III.

In light of the foregoing arguments, it can be concluded that the claims of provisionally elected Group II contain multiple unifying features with the claims of Groups I, III and IV. Hence, it is believed that a single search of the features of the claims of Group II would necessarily and unescapably require a search of the subject matter of the claims of Groups I, III and IV.

In closing, applicants respectfully submit that the groups of claims designated by

the Examiner fail to define methods and compositions that warrant separate examination and search. The present claims represent a web of knowledge and continuity of effort that merits examination in a single application. The search and examination of each group is necessarily co-extensive, and in any event would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner. Accordingly, applicants respectfully request that the Examiner withdraws the Requirement for Restriction and examines all of the pending claims in a single application or at least modifies the Requirement to allow prosecution of more than one of the above groups.

## CONCLUSION

Applicants request entry of the foregoing remarks in the file history of this application. In view of the above arguments, withdrawal or modification of the Requirement for Restriction is respectfully requested, and an early action on the merits is courteously solicited.

Respectfully submitted,

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